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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,050	08/20/2001	Clifford Charles Shone	1581.0800000	8265

7590 01/13/2005

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EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/831,050	Applicant(s) SHONE ET AL.	
	Examiner Sandra Wegert	Art Unit 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 7 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 20 September 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.


Claim(s) objected to: _____.

Claim(s) rejected: 25,29-33,36,42,43.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

Continuation of 5. does NOT place the application in condition for allowance because: 35 USC § 112, enablement issues remain. The disclosure is not enabling for use of the composition to translocate SOD into neuronal cells and thereby reduce oxidative damage. It is not known, and not explained in the 9/20/04 Response, how absorbance of light at 570nm is related to oxidative stress. No experiments were performed demonstrating that the SOD/Clostridium composition was translocated into the NG-108 cells. No evidence was presented that the cells were oxidatively stressed or damaged. The treatment groups seem indistinguishable from each other and there appears to be no concentration effect of superoxide dismutase on the measured variable. Furthermore, evidence from others indicates that NG-108 cells lack receptors for botulinum peptides (Yokasawa, et al, 1991, Toxicon., 29(2): 261-264; Yokasawa, et al, 1989, Infect. Immun., 57(1): 272-277). Furthermore, Applicants also argued that use of potassium ions in the experimental baths provides evidence of neuronal stimulation of the NG-108 cells, when in fact potassium has a neutral or inhibitory effect on most cells, especially neuronal cells. Finally, independent claims read on a composition for treating any neuronal cells, including those in vivo, and are not confined to a composition applied only to glioma cells in a monolayer culture.



ELIZABETH KEMMERER
PRIMARY EXAMINER